

### **Remarks**

#### **Status of the Claims**

Upon entry of the present amendment, claims 76-92 and 94-106 will be pending in the application. Claims 76-91 and 98-104 are currently withdrawn from consideration. Claim 93 has been cancelled herein. Claim 92 has been amended to be rewritten into independent form and to include the subject matter of claim 76 as originally filed. Claim 97 has been amended to depend from claim 92. Support for new claims 105-106 can be found in the specification, *inter alia*, at page 92, lines 9-17. No new matter has been added.

#### **Issues under 35 U.S.C. § 112, first paragraph**

The Examiner has rejected claims 92-97 under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for the prevention of gastrointestinal bacterial infections or the treatment/prevention of all bacterial infections. Applicants have amended claim 92 to be directed to “gastrointestinal infection” rather than “bacterial infection.”

With respect to the alleged lack of enablement for the prevention of gastrointestinal infections, Applicants respectfully traverse.

As reviewed by Beachey, 1981 (cited in the IDS concurrently filed herewith) and also as a repeatedly shown fact in the art that carbohydrate mediated binding is a key pathogenic mechanism in microbial infections, Applicants respectfully submit that the term “prophylactically” in claim 92 is enabled by the present specification. The Examiner’s discussion of other factors may affect this key pathogenic mechanism, but

these other factors have marginal effect in comparison with the carbohydrate mediated mechanisms in pathogenesis. Further, it is generally accepted in the art that adhesion of a pathogen to a host tissue is required for infection and that carbohydrate mediated adhesion is the key mechanism known for adhesion.

For example, Prieto et al. '854 (US 6,045,854), cited by the Examiner, also disclose the preventive or prophylactic mode of action of carbohydrates. The Examiner acknowledges this mechanism at the bottom of page 4 and top of page 5 of the outstanding Office Action ("Prieto et al. (US 6,045,854, of record) teach that oligosaccharides protect infants from bacterial infections....").

Applicants further note that, in numerous patents granted by the U.S.P.T.O. related to other pathogen receptor types/infections, i.e. U.S. Patent No. 5,665,561 (Tuomanen et al.; claim 14) and No. 6,664,235 (Kanie et al.; claim 4), the embodiment of prevention has been allowed when the subject matter of the application has been related to carbohydrate mediated mechanisms in pathogenesis and it has been shown that the use of a saccharide prevents the binding of the pathogen to the host tissue as is also the case in the present application.

Therefore, as previously admitted by other Examiners of the U.S.P.T.O., one of ordinary skill in the art would understand that the same carbohydrate, which has activity in inhibiting binding of bacterial pathogens to host tissue such as the gastrointestinal tract in this case, also has prophylactic activity in preventing the pathogen binding and thus the infection.

For the reasons given above in view of the amended claim 92, Applicants respectfully submit that the outstanding rejection has been overcome and should be removed.

**Issues under 35 U.S.C. § 112, second paragraph**

The Examiner has rejected claims 92-97 under 35 U.S.C. § 112, second paragraph, as being indefinite.

First, the Examiner asserts that claim 92 should be rewritten into independent form since claim 76 is currently withdrawn from consideration. Applicants have amended claim 92 to be rewritten into independent form. Thus, Applicants respectfully submit that the amendment overcomes the outstanding rejection and that the rejection be removed.

Second, the Examiner alleges that the limitation “a therapeutical composition containing purified fraction(s) of at least two compounds” is indefinite because “containing” is open language, which permits the inclusion of elements, such as impurities, other than purified fraction(s) in the composition. Applicants respectfully traverse.

One of ordinary skill in the art would understand that, when an oligosaccharide fraction is produced (purified/isolated), non-oligosaccharide material is removed to obtain the purified fraction of oligosaccharide material. However, therapeutic compositions may still include other materials than the active compound or fraction. Thus, the term “containing” should be allowed in the claims. For these reasons,

Applicants respectfully submit that the outstanding rejection has been overcome and should be removed.

**Issues under 35 U.S.C. § 102(b)**

The Examiner has rejected claims 92-97 under 35 U.S.C. § 102(b) as being anticipated by Pickering et al. (Infection 21 (1993) No. 6, pages 355-357). Claim 93 has been cancelled herein, which renders the rejection as to this claim moot. With respect to the remaining claims, Applicants respectfully assert that Pickering et al. do not disclose each and every aspect of, at least, independent claim 92, from which claims 94-97 depend.

The Examiner refers to Pickering et al. relating to protective actions of human milk. It is also true that human milk contains LnNT and Neu5Ac $\alpha$ 3Gal $\beta$ 4Glc. However, it is also known that human milk contains numerous active components. Pickering et al. do not refer to the specific saccharides. Therefore, it is not possible to anticipate the present invention based on Pickering et al.

Applicants respectfully submit that the analysis of Pickering et al. is based on retrospective consideration using the information derived from the present invention.

Applicants also traverse the interpretation that “the free LnNT and Neu5Ac $\alpha$ 3Gal $\beta$ 4Glc in human milk can be considered purified fractions within the milk composition.” Human milk is a complex composition containing various oligosaccharides. One of ordinary skill in the art would know that free LnNT and Neu5Ac $\alpha$ 3Gal $\beta$ 4Glc do not occur as purified fractions within the milk composition.

In view of the above, Applicants therefore respectfully submit that claim 92, and those dependent thereon, clearly distinguish over Pickering et al. Accordingly, independent claim 92 as well as its dependent claims is therefore novel and non-obvious over Pickering et al.

**Newly Proposed Claims 105-106**

Applicants have newly proposed claims 105-106 in an effort to more clearly define the scope of protection owed to Applicants. Specifically, claims 105-106 further define the term “purified fraction(s).” Applicants respectfully submit that claims 105-106 are allowable for the reasons given above.

With respect to the rejection under 35 U.S.C. § 102(b) above, claim 105 is presented to define the purified fraction as “purified or isolated oligosaccharide fraction(s) from natural or synthetic sources.” Human milk is a natural source and does not contain separate purified isolated fractions of the two oligosaccharides nor synthetic oligosaccharides. Applicants do not find any indication from Pickering et al. about “purified or isolated oligosaccharide fraction(s) from natural or synthetic sources” as natural human milk is consumed as such, and not as specific oligosaccharide fractions.

In view of the above, Applicants respectfully assert that claims 105-106 clearly define over the prior art of record, and an early action to this effect is earnestly solicited.

**CONCLUSION**


In view of the above, Applicants submit that the present claims are in condition for allowance. Thus, the Examiner is requested to withdraw all rejections and allow the currently pending and examined claims.

If the Examiner has any questions or comments, please contact Chad A. Rink, Registration No 58,258, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: JUN 27 2008

Respectfully submitted,

By 

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